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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/974,584	11/19/97	CECH	T 015389-00295

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HM12/0926

EXAMINER

MYERS, C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

09/26/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/974,584

Applicant(s)

CECH et al

Examiner

Carla Myers

Group Art Unit

1655

☒ Responsive to communication(s) filed on Mar 30, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-104 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-104 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Sequence listing + Notice to compy

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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1. Applicant's response of Paper No. 9, filed March 30, 1999 is acknowledged. In the response of Paper No. 9, Applicant elected group II, claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93 and did not specifically traverse the previous restriction requirement. However, in order to maintain consistency between the present application and Applicant's copending applications, the following new restriction requirement is made.

2. ***RESTRICTION***

Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the method claims in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The method claims are improperly joined as the claims require the use of specific nucleic acid and proteins isolated from distinct organisms. A reference against one nucleic acid or protein would be a reference against another nucleic acid or protein molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92, and 94-104, drawn to *Euplotes aediculatus* telomerase RT proteins, classified in Class 530, subclass 350.

2. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92, and 94-104, drawn to *Oxytricha* telomerase RT proteins, classified in Class 530, subclass 350.

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3. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92, and 94-104, drawn to *Schizosaccharomyces* telomerase RT proteins, classified in Class 530, subclass 350.
4. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92, and 94-104, drawn to *Saccharomyces* telomerase RT proteins, classified in Class 530, subclass 350.
5. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92, and 94-104, drawn to Human telomerase RT proteins, classified in Class 530, subclass 350.
6. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92, and 94-104, drawn to *Tetrahymena* telomerase RT proteins, classified in Class 530, subclass 350.
7. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to *Euplotes aediculatus* telomerase RT (TRT) nucleic acids, methods of detecting said nucleic acids, vectors and host cells containing said nucleic acids and pharmaceutical compositions, classified in Class 435, subclass 6, Class 536, subclass 23.1 and Class 514, subclass 44.
8. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to *Oxytricha* telomerase RT (TRT) nucleic acids, methods of detecting said nucleic acids, vectors and host cells containing said nucleic acids and pharmaceutical compositions, classified in Class 435, subclass 6, Class 536, subclass 23.1 and Class 514, subclass 44.
9. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to *Schizosaccharomyces* telomerase RT (TRT) nucleic acids, methods of detecting said nucleic acids, vectors and host cells containing said nucleic acids and pharmaceutical compositions, classified in Class 435, subclass 6, Class 536, subclass 23.1 and Class 514, subclass 44.

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10. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to *Saccharomyces* telomerase RT (TRT) nucleic acids, methods of detecting said nucleic acids, vectors and host cells containing said nucleic acids and pharmaceutical compositions, classified in Class 435, subclass 6, Class 536, subclass 23.1 and Class 514, subclass 44.

11. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to Human telomerase RT (TRT) nucleic acids, methods of detecting said nucleic acids, vectors and host cells containing said nucleic acids and pharmaceutical compositions, classified in Class 435, subclass 6, Class 536, subclass 23.1 and Class 514, subclass 44.

12. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to *Tetrahymena* telomerase RT (TRT) nucleic acids, methods of detecting said nucleic acids, vectors and host cells containing said nucleic acids and pharmaceutical compositions, classified in Class 435, subclass 6, Class 536, subclass 23.1 and Class 514, subclass 44.

13. Claims 25-32, drawn to transgenic animals containing *Euplotes aediculatus* nucleic acids, classified in Class 800, subclass 18.

14. Claims 25-32, drawn to transgenic animals containing *Oxytricha* nucleic acids, classified in Class 800, subclass 18.

15. Claims 25-32, drawn to transgenic animals containing *Schizosaccharomyces* nucleic acids, classified in Class 800, subclass 18.

16. Claims 25-32, drawn to transgenic animals containing *Saccharomyces* nucleic acids, classified in Class 800, subclass 18.

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17. Claims 25-32, drawn to transgenic animals containing Human nucleic acids, classified in Class 800, subclass 18.

18. Claims 25-32, drawn to transgenic animals containing *Tetrahymena* nucleic acids, classified in Class 800, subclass 18.

19. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for *Euplotes aediculatus* TRTs, detection assays using said antibodies and pharmaceutical compositions containing said antibodies, classified in Class 530, subclass 387.9, and Class 435, subclass 7.1.

20. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for *Oxytricha* TRTs, detection assays using said antibodies and pharmaceutical compositions containing said antibodies, classified in Class 530, subclass 387.9, and Class 435, subclass 7.1.

21. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for *Schizosaccharomyces* TRTs, detection assays using said antibodies and pharmaceutical compositions containing said antibodies, classified in Class 530, subclass 387.9, and Class 435, subclass 7.1.

22. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for *Saccharomyces* TRTs, detection assays using said antibodies and pharmaceutical compositions containing said antibodies, classified in Class 530, subclass 387.9, and Class 435, subclass 7.1.

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23. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for human TRTs, detection assays using said antibodies and pharmaceutical compositions containing said antibodies, classified in Class 530, subclass 387.9, and Class 435, subclass 7.1.

24. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for *Tetrahymena* TRTs, detection assays using said antibodies and pharmaceutical compositions containing said antibodies, classified in Class 530, subclass 387.9, and Class 435, subclass 7.1.

25. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate *Euplotes aediculatus* TRT activity, classified in Class 435, subclass 4.

26. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate *Oxytricha* TRT activity, classified in Class 435, subclass 4.

27. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate *Schizosaccharomyces* TRT activity, classified in Class 435, subclass 4.

28. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate *Saccharomyces* TRT activity, classified in Class 435, subclass 4.

29. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate Human TRT activity, classified in Class 435, subclass 4.

30. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate *Tetrahymena* TRT activity, classified in Class 435, subclass 4.

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31. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of *Euplotes aediculatus* TRT-classification cannot be determined without further information.

32. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of *Oxytricha* TRT-classification cannot be determined without further information.

33. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of *Schizosaccharomyces* TRT-classification cannot be determined without further information.

34. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of *Saccharomyces* TRT-classification cannot be determined without further information.

35. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of Human TRT-classification cannot be determined without further information.

36. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of *Tetrahymena* TRT-classification cannot be determined without further information.

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37. Claims 45 and 46, drawn to the use of an unspecified agent which increases expression or activity of *Euplotes aediculatus* TRT in the manufacture of a medicament-classification cannot be determined without further information.

38. Claims 45 and 46, drawn to the use of an unspecified agent which increases expression or activity of *Oxytricha* TRT in the manufacture of a medicament-classification cannot be determined without further information.

39. Claims 45 and 46, drawn to the use of an unspecified agent which increases expression or activity of *Schizosaccharomyces* TRT in the manufacture of a medicament-classification cannot be determined without further information.

40. Claims 45 and 46, drawn to the use of an unspecified agent which increases expression or activity of *Saccharomyces* TRT in the manufacture of a medicament-classification cannot be determined without further information.

41. Claims 45 and 46, drawn to the use of an unspecified agent which increases expression or activity of Human TRT in the manufacture of a medicament-classification cannot be determined without further information.

42. Claims 45 and 46, drawn to the use of an unspecified agent which increases expression or activity of *Tetrahymena* TRT in the manufacture of a medicament-classification cannot be determined without further information.

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43. Claim 48, drawn to the use of an unspecified agent which inhibits expression of *Euplotes aediculatus* TRT in the manufacture of a medicament-classification cannot be determined without further information.

44. Claim 48, drawn to the use of an unspecified agent which inhibits expression of *Oxytricha* TRT in the manufacture of a medicament-classification cannot be determined without further information.

45. Claim 48, drawn to the use of an unspecified agent which inhibits expression of *Schizosaccharomyces* TRT in the manufacture of a medicament-classification cannot be determined without further information.

46. Claim 48, drawn to the use of an unspecified agent which inhibits expression of *Saccharomyces* TRT in the manufacture of a medicament-classification cannot be determined without further information.

47. Claim 48, drawn to the use of an unspecified agent which inhibits expression of Human TRT in the manufacture of a medicament-classification cannot be determined without further information.

48. Claim 48, drawn to the use of an unspecified agent which inhibits expression of *Tetrahymena* TRT in the manufacture of a medicament-classification cannot be determined without further information.

The inventions are distinct, each from the other because of the following reasons:

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Inventions 1-6, inventions 7-12, inventions 13-18, inventions 19-24, inventions 25-30, inventions 31-36, inventions 37-42, and inventions 43-48 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the different inventions are drawn to structurally distinct proteins which differ in their amino acid sequence, structurally distinct polynucleotides which differ in their nucleotide sequence, structurally distinct antibodies which differ in their specificity and in their amino acid sequence and methods of using said structurally distinct proteins and polynucleotides.

Furthermore, inventions 1-24 represent separate and distinct inventions, as they are made by and used in separate methods. In particular, polynucleotides are structurally and functionally distinct over proteins and antibodies because polynucleotides are composed of nucleotides, whereas proteins and antibodies are composed of amino acids. Polynucleotides are used in methodologies that are distinct over that of proteins and antibodies in that polynucleotides may be used in hybridization methods, whereas proteins may be used in methods for identifying compounds which bind to the protein and antibodies may be used in methods for isolating protein or in methods of treatment. The polynucleotides are not required for the synthesis of the claimed proteins because the proteins can be chemically synthesized or isolated from natural sources. The proteins and antibodies are also structurally distinct in that they consist of unique amino acid sequences and have different functional properties. The proteins and antibodies may be utilized in distinct methods, such that proteins may be used in methods for identifying compounds which

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bind to the protein and antibodies may be used in methods of treatment. Transgenic animals have structurally distinct characteristics over polynucleotides and are used in separate methods, such as for studying disease or in treatment methodologies. Moreover, the methodologies of claims 25-48 are distinct and unobvious over each other because the individual methodologies require different reagents, involve different method steps and have different objectives and outcomes.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions 1-48 require different keyword and sequence searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Furthermore, the reply must include an identification of all claims corresponding to the elected invention, including any subsequently added claims and the SEQ ID NO.'s corresponding to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821-25 for the reasons set forth on the accompanying Notice to Comply with Requirements For Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures. It is noted that Applicants petition to waive the "Sequence Rules" has been denied. Accordingly, Applicants must comply with the requirements of 37 CFR 1.821-1.825 in response to this Office action. In particular, Applicant is required to submit a CRF copy of the Sequence Listing containing the disclosed sequences and a letter stating that the content of the paper and computer readable copies are the same.

4. A substitute specification and claims is required pursuant to 37 CFR 1.125(a) because the number and nature of the amendments set forth in Paper No. 9 render the specification difficult to consider and difficult to arrange the papers for printing or copying (see 37 CFR 1.125).

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

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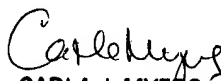
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

September 25, 2000

  
CARLA J. MYERS  
PRIMARY EXAMINER